PRIOR AUTHORIZATION POLICY

POLICY: Graft-Versus-Host Disease – Rezurock Prior Authorization Policy
- Rezurock® (belumosudil tablets – Kadmon)

REVIEW DATE: 05/07/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Rezurock, a kinase inhibitor, is indicated for the treatment of **chronic graft-versus-host disease** (GVHD) in patients ≥ 12 years of age after failure of at least two prior lines of systemic therapy.[1]

Guidelines

Rezurock has been addressed in the National Comprehensive Cancer Network Hematopoietic Cell Transplantation guidelines (version 1.2025 – February 28, 2025). Options for first-line therapy for chronic GVHD including restarting, continuing, or escalating the original immunosuppressive agent(s) and/or administering systemic corticosteroids (0.5 to 1 mg/kg day of methylprednisolone or prednisone dose equivalent). Among the agents FDA-approved for use in chronic GVHD, Jakafi® (ruxolitinib tablets) is the only agent given a category 1 recommendation for chronic GVHD. Rezurock, Niktimvo™ (axatilimab-csfr intravenous infusion), and Imbruvica® (ibrutinib tablets, capsules, and oral suspension) each have a category 2A

recommendation. The guidelines cite that each of these FDA-approved agents should be used following failure of one or two lines of systemic therapy (depending on the agent). Other medication alternatives include Orencia® (abatacept intravenous [IV] infusion and subcutaneous [SC] injection), Lemtrada® (alemtuzumab IV infusion), calcineurin inhibitors (e.g., tacrolimus, cyclosporine), Enbrel® (etanercept SC injection), extracorporeal photopheresis, hydroxychloroquine, imatinib, Proleukin® (aldesleukin IV infusion and SC injection), low-dose methotrexate, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, pentostatin, and rituximab.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rezurock. All approvals are provided for the duration noted below.

- **Rezurock® (belumosudil tablets - Kadmon)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Graft-Versus-Host Disease.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient has chronic graft-versus-host disease; AND
     - **iii.** Patient has tried at least two systemic medications for chronic graft-versus-host disease; OR

       Note: Examples of systemic medications include Jakafi (ruxolitinib tablets), Niktimvo (axatilimab-csfr intravenous infusion), Imbruvica (ibrutinib capsules, tablets, or oral solution), imatinib, hydroxychloroquine, methotrexate, rituximab, pentostatin, interleukin-2 (e.g., Proleukin [aldesleukin intravenous infusion]), methylprednisolone, cyclosporine, tacrolimus, sirolimus, an etanercept product, and mycophenolate mofetil.
   - **B)** Patient Currently Receiving Rezurock. Approve if according to the prescriber, the patient demonstrates a beneficial clinical response.

     Note: Examples of a beneficial response include a reduction in corticosteroid dose, disease stabilization, and/or symptomatic improvement.

CONDITIONS NOT COVERED

- **Rezurock® (belumosudil tablets - Kadmon)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Rezurock® tablets [prescribing information]. Bridgewater, NJ: Kadmon; January 2024.
2. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 1.2025 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.ncc.org. Accessed on March 19, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/16/2023
Annual Revision	No criteria changes.	08/21/2024
Early Annual Revision	The header was changed from "Immunosuppressive Agents" to "Graft-Versus-Host Disease". **Graft-Versus-Host Disease:** The criteria were divided into "Initial Therapy" and "Patient Currently Receiving Rezurock". For initial therapy, for the requirement that a patient tried two systemic treatments, the descriptor "conventional" was removed and the word "therapies" was changed to "medications". Also, the Note that cites examples of systemic medications for chronic graft-versus-host disease was updated to add the following: Jakafi (ruxolitinib tablets), Niktimvo (axatilimab-csfr intravenous infusion), hydroxychloroquine, methotrexate, rituximab, pentostatin, interleukin-2 (e.g., Proleukin [aldesleukin intravenous infusion]), and an etanercept product. For a patient currently receiving Rezurock, an approval is given if according to the prescriber, the patient demonstrates a beneficial clinical response. A Note was added that a beneficial response can include a reduction in corticosteroid dose, disease stabilization, and/or symptomatic improvement.	05/07/2025